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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,669	08/16/2001	Masahiro Sakanaka	56238(71526)	4547

21874 7590 06/01/2005

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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,669	SAKANAKA ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-36,38-44,52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36,38-44,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and remarks filed on 03/07/2005 are acknowledged. New claims 52 and 53 have been added. Claims 1-31, 37 and 45-51 have been cancelled. Claims 32-36 have been amended.

A terminal disclaimer filed on 2/28/2003 over application 09/887,399, now issued as U.S. Patent 6,579,853 has been accepted.

Claims 32-36, 38-44, 52 and 53 are currently pending in this application.

35 U.S.C. 112, first paragraph rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-36, 38-44 and newly added claims 52-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention of record. The specification, while enabling a method of inducing apoptosis or apoptosis-like cell death of oligodendrocytes comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1, does not reasonably provide enablement for the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, a method for the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside

Rb_1 would require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be provided. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation, to treat the diseases caused by injuries to nervous tissues.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of an effective amount of ginsenoside Rb_1 in a method for the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, for the treatment of human health conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of an effective amount of the ginsenoside Rb_1 and the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords. No guidance to use the ginsenoside Rb_1 for the treatment of diseases caused by injuries to nervous tissues or the spinal cord.

3. WORKING EXAMPLES IN SPECIFICATION

The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breadth of the claims for the treatment of diseases caused by injuries to

nervous tissues or the spinal cord. It is noted that Examples 1-9 provide intravenous infusion of ginsenoside Rb_1 and treatment of bedsore, corneal injury, chorea and dilated cardiomyopathy.

4. NATURE OF THE INVENTION

It is known in this art that certain compounds from ginseng root have efficacy in treating cerebral vascular disease. The exact mechanism of action and the effects of these compounds may be found in the U.S. Patent 4,708,949 (Liu).

5. STATE OF THE PRIOR ART

The instant claimed methods are drawn to a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord. The following references are cited to show the state of the prior art:

Liu, U.S. Patent 4,708,949.

Lim et al., Neuroscience Res. 28, 191-200, 1997.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from ginsenoside Rb_1, for the treatment of the diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords not seen to be disclosed in the prior art. Neither the specification nor the prior art provides adequate guidance for equivocating the treatment data for the ginsenoside Rb_1, the treatment of diseases caused by injuries to nervous tissues or the spinal cord. The asserted treatment of diseases caused by injuries to nervous tissues is not seen to be based upon data which would adequately substantiate the treatment of

diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords in a subject in need thereof.

7. BREATH OF THE CLAIMS

Claims 32-36, 38-44, 52 and 53 are drawn to a method for the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to a method for the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords, is that of a Ph.D. or M.D. level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims, which encompass a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of ginsenoside Rb_1 for the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are

spinal cords would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

Rejection Maintained

Applicant's arguments filed on 03/07/05 traversing the rejection of claims 32-36, 38-44 under 35 U.S.C. 112, first paragraph have been fully considered but they are not persuasive. These arguments also fail to obviate the rejection of newly added claims 52 and 53.

Response to Arguments

Applicants argue that "applicant have amended claim 32 and dependent claims 33-36 to be directed to wards traumatic or compression injuries to nervous tissues".

The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation, the treatment of diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords comprising administering to a patient an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1. Although applicant alleges that their invention is enabled for the experimentation in Example 4, "which demonstrates the effect of ginsenoside Rb_1 for the treatment caused by injuries to spinal cord", the instant disclosure appears to be limited to the effect of intravenous infusion of ginsenoside Rb_1 on rats with spinal cord injuries. The specification, while enabling the effect of intravenous infusion of ginsenoside Rb_1 on rats with spinal cord injuries, does not reasonably provide enablement for the treatment of

diseases caused by traumatic or compression injuries to nervous tissues wherein the nervous tissues are spinal cords comprising administering to a patient.

Applicant's amendment adding claims 52 and 53 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be

reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
May 24,2005

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600